[(cyclohexylmethylen)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)-pregna-1,4-dien-3,20-dion and is present in any mixing ratio with ciclesonide, [11β,16α(R)]-16,17-[(cyclohexylmethylen)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)-pregna-1,4-dien-3,20-dion.

20. The method of claim 18, wherein said mammal is a human.

REMARKS

Claims 1-16 and 18-20 are currently pending in the present application, which are directed to a pharmaceutical composition comprising a combination of antihistamine and ciclesonide for use in the treatment of allergic rhinitis and the treatment method using the composition.

Claim 15 has been amended to replace the brackets with parentheses and to delete the term "INN". Claim 19 has been amended to more clarify both the terms of "ciclesonide" and "epimer of ciclesonide" with their chemical names. No new matter has been introduced to the claims within the meaning of 35 U.S.C. §132. Accordingly, entry of the amendments is respectfully requested.

In view of the amendment to claim 15 as described above, the Examiner's objection to claim 15 has been overcome.

For the claim rejections, further and favorable consideration is respectfully requested in view of the following.

1. Rejection of Claim 19 Under 35 U.S.C. §112 2nd Paragraph

The Official Action states in the relevant part that claim 19 is rejected under 35

U.S.C. §112 2nd paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

As the basis of the rejection, the Official Action states in relevant part:

> ...Applicant's claim is to a pharmaceutical composition of an antihistamine and ciclesonide, wherein an epimer of ciclesonide may be utilized (claim 1); because ciclesonide has a chiral carbon, both an R-epimer and an S-epimer could exist as well as a racemate mixture of the two epimers. Since Applicant's specification fails to teach whether the term "ciclesonide" refers to the R-epimer, S-epimer or the racemic mixture of both epimers, one of ordinary skill in the art cannot ascertain how to determine what a mixing ratio with ciclesonide encompasses and thus is indefinite.

Applicant respectfully traverses this rejection. The subject matter of the rejected claim would be perfectly clear to the ordinary skilled artisan when read in light of the specification. In this regard, applicants respectfully direct the Examiner's attention to the instant specification which is replete with disclosure as to the meaning of the terms "ciclesonide" and "epimer of ciclesonide".

In particular, applicant submits that the instant specification clearly describes at page 5, last paragraph, that "ciclesonide" is the International Nonproprietary Name (INN) for a compound with the following chemical name: [11β,16α**(R)**]-16,17-[(cyclohexylmethylen)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)-pregna-1,4-dien-3,20-dion. The term "ciclesonide" does not refer to a racemic mixture of the two epimers. It refers to the **R-epimer** only. Similarly, the term "epimer of ciclesonide" in claim 19 refers to [11β,16α**(S)**]-16,17-[(cyclohexylmethylen)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)-pregna-1,4-dien-3,20-dion, i.e., the S-epimer, as taught at the same page of the specification.

Further, in order to clarify this distinction, applicant has amended claim 19 to

include the chemical name of ciclesonide and the epimer thereof, respectively, in accordance with the disclosure at page 5 of the instant specification.

In view of this description in the present specification and the present claim amendments, the terms "ciclesonide" and "mixing ratio with ciclesonide" in claim 19 should be considered as both clear and definite. Accordingly, the Examiner is respectfully requested to withdraw this rejection of pending claim 19.

2. Rejection of Claims 1-16 and 18-20 under 35 U.S.C. §103(a)

The Official Action states in the relevant part that claims 1-16 and 18-20 are rejected under 35 U.S.C. 103(a) as being obvious over Nagano et al. (US 6,767,901) in view of Nishibe et al. (US Application Publication 2003/0008019).

As the basis of the rejection, the Official Action states in relevant part:

> ... Nagano et al. has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another:; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject mater disclosed but not claimed in the reference, prior to the effective US filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(C). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(C) as prior art in a rejection under 35 U.S.C. 103(a).
>
> ... Both Nagano et al. and Nishibe et al. teach aqueous pharmaceutical compositions which are applied to mucosa using solutions possessing different osmotic pressures (mOsm) resulting in an improved bioavailability of medicaments. The pharmaceutical composition of

> Nagano et al. discloses that the steroid, ciclesonide, is absorbed by the mucosa and retained locally thus limiting its harmful systemic effects and instead, increasing its pharmacological effectiveness. Nishibe et al. teaches that aqueous solutions with low osmotic pressure are beneficial for agents that are applied to the mucosa, such as those agents used for the treatment of allergies. Included among the anti-allergy agents are antihistamine drugs, such as ... ... which are used in the treatment of rhinitis (allergic) and asthma (22nd paragraph, in its entirety), however this list of steroids does not include ciclesonide. Because the aqueous solution composition containing ciclesonide, taught by Nagano et al. demonstrated (1) limited systemic effects, (2) improved bioavailability and (3) increased pharmacological effectiveness when the aqueous solution had a low osmotic pressure, it would have been prima facie obvious, to one of ordinary skill in the art, to substitute ciclesonide for one of the steroids taught by Nishibe et al. in order to formulate a combination drug for treatment of allergy symptoms and asthma with lower risk of systemic side effects, improved bioavailability and increased pharmacological effectiveness.

Applicant respectfully traverses this rejection of claims 1-16 and 18-20. The cited references do not establish a *prima facie* case of obviousness against the presently pending claims.

To establish a prima facie case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court recently held in KSR International Co. v. Teleflex Inc. et al., Slip Opinion No. 04-1350, 550 U.S. (April 30, 2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted

a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (KSR, supra, slip opinion at 13-15). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. Amgen Inc. v. Chugai Pharm. Co., 18 USPQ 1016, 1023 (C.C.P.A 1970). Lastly, the prior art references must teach or suggest all the limitations of the claims. In re Wilson, 165 USPQ 494, 496 (C.C.P.A. 1970).

The Nagano reference cited by the Examiner, U.S. Patent No. 6,767,901 is commonly owned with the present application. Further, this reference is only available for use in the present obviousness rejection under 35 U.S.C. § 102(e). Accordingly, this reference is thus disqualified as prior art for the purposes of the present rejection under 35 U.S.C. § 103(c).

In particular, at the time the present application was filed the Nagano reference was assigned to Altana Pharma AG, as recorded by the U.S. PTO on July 15, 2002 at Reel 013085, Frame 0968. Likewise, the present application at the time of filing was assigned to Altana Pharma AG. The name Altana Pharma AG has since been changed to Nycomed GmbH and recorded by the USPTO at Reel 019783, Frame 0625 on September 4, 2007. Accordingly, the Nagano reference was commonly owned with the present application at the time the present application was filed, and remains commonly owned with the present application.

Accordingly, since the Nagano reference is commonly owned with the present application, it is thus disqualified as a prior art reference for the purposes of the present rejection under 35 U.S.C. § 103(c). As such, the Examiner's obviousness rejection relying on the combination of Nagano et al. and Nishibe et al. lose its effect due to the disqualification of the reference Nagano et al. as prior art.

Taking Nishibe et al. alone, it can not make the presently claimed subject matter obvious since it fails to disclose "ciclesonide". To establish a *prima facie* case of obviousness, the prior art reference(s) must, *inter alia,* teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970). Nishibe et al. does not disclose ciclesonide itself and cannot teach the presently claimed subject matter directed to the pharmaceutical composition comprising a combination of antihistamine and ciclesonide.

The Examiner is respectfully requested to withdraw this rejection of presently pending claims 1-16 and 18-20.

CONCLUSION

Based upon the remarks, the presently claimed subject matter is believed not only to distinctly claim the subject matter but also to be patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw the outstanding rejections and allow all pending claims 1-16 and 18-20. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if he has any

questions or comments. In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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